# Safety in Healthcare Delivery and Research

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Acting Chief Health and Medical Officer
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### **OCHMO** Mission

The CHMO assists the Administrator to ensure the health and safety of NASA employees in space and on the ground by establishing guidelines for health and medical practice in the Agency, developing health and medical policy, providing oversight of health care delivery and professional competency Agency-wide, and reviewing/validating research requirements and deliverables. The CHMO also monitors human and animal research and clinical practice to ensure that the Agency adheres to the highest medical and ethical standards and satisfies all regulatory and statutory requirements.





# NASA Headquarters Organization

#### NASA ADMINISTRATOR

Deputy Administrator
Chief of Staff
Chief Engineer
Chief Financial Officer
Chief Technologist
Chief Health and Medical Officer
Chief Scientist

Code U
Code R
Code M
Code Y
Code S

Health
Research
Space Medical Operations





### Office of Chief Health and Medical Officer (Code AM)







### Medical Boards in Support of NASA Health Care

#### Medical Policy Board (HQ)

- Medical policy for space medicine, atmospheric flight, and occupational health
- Permanent medical waiver authority
- Reviews/approves selection and retention medical standards
- Review of salient space medicine issues with recommendations to the Office of Space Flight as appropriate
- Tracks reviews of health research requirements and deliverables

#### Aerospace Medicine Board (JSC)

- Clinical board
- Temporary waiver authority
- Develops standards

#### Health Council (HQ)

CHMO chairs





### Occupational Health

- Major roles and responsibilities remain unchanged
  - Seamless transition
  - Staff remains the same
- Principal Center remains responsible for implementation oversight
- Primary administrative support for Health Council
- Headquarters oversight for Medical Quality Improvement and Assurance Effort
  - Medical Quality Improvement Expert





### Quality Improvement and Assurance

#### Credentials and Privileging Process

- Cornerstone of practice
- Medical Staff Review Functions
- Administrative and clinical

#### Periodic Site Visits

- Emphasis on safety of practice, infection control, etc.
- Checklist Methodology
- Principal Center, augmented as necessary
- JCAHO influence

#### Medical Quality Assurance Program

- Protected incident investigation methodology





# Professional Education and Development

- Aerospace Medicine Residencies
  - University of Texas Medical Branch, Galveston
  - Wright State University
- East-West Space Science Center
- Sponsorship of workshops and skills development seminars
- Video-teleconference series on Selected Health Topics
  - 2 per year
  - 15-20 hours CME offered per series





### Continuing Medical Education

Occupational Health Policies

**Public Health Policies** 

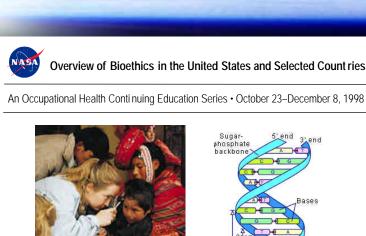
**Bioethics** 

Health Surveillance and Maintenance in the Workplace

**Emerging Diseases** 

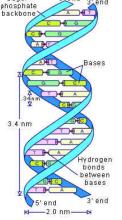
Aging

99 Hours CME Delivered















- Clear distinction between motives of investigators and research subjects
- Potential conflict between need to test hypotheses and requirement to respect and protect subjects
- Many prospective research subjects believe medical research connotes benevolence
- History of abuse and exploitation
  - Tuskegee Syphilis Study
  - Human radiation studies
- Oversight is required to ensure abuses do not occur, and to ensure adequate safety measures are present for participants



- 1994 Advisory Committee on Human Radiation Experiments (ACHRE) created
  - Investigate reports of federally sponsored human research involving radioactive materials
  - Assess current state of protection for research participants
- 1995 National Bioethics Advisory Commission established
- 1997 "No person in the United States should be enrolled in research without the twin protections of informed consent by an authorized person and independent review of the risks and benefits of the research"
- "We must never allow our citizens to be unwitting guinea pigs in scientific experiments that put them at risk without their consent and full knowledge" Clinton, 1997



- NASA is a research organization
- Human research is necessary to develop countermeasures to microgravity and the extreme environment of space
- Human research will be necessary to develop the evidence base to support the practice of medicine in space
- Animal research is necessary to explore the fundamental biology of microgravity
- NASA Institutional Review Boards and the NASA Animal Care and Use Committee exist to protect the health and safety of human research subjects and to assure the ethical and humane treatment of animal research subjects



#### Astronauts as Research Subjects

- No other opportunities for research subjects on orbit at present
- No immediate benefit for Astronauts as participants in research, may benefit subsequent crewmembers
- Astronauts begin in good health why volunteer to participate in research that may involve risks?
- Why volunteer to participate in additional physiological or psychological tests that may reveal a medical problem?
- Investigator/subject dynamics are particularly difficult

### Flight Surgeons

- Primary purpose is to care for the crewmembers
- Essential link in NASA human research





### OCHMO Role

- Serve as a center of excellence for Bioethics in the Agency and for the Nation
- Provide review and oversight for NASA IRB and ACUC activities
- Provide expertise to investigate untoward events if necessary
- Liaison to NBAC
- Work with NASA Chief Scientist to help address research integrity issues (if required)



## Health Care in Space - Long Duration Flight

primary prevention secondary prevention

tertiary prevention

Pi	e	f	io	ht
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Preventive Health
Screening/Countermeasures

Preventive Health Screening/Improved Countermeasures Preventive Health
Screening/Advanced
Countermeasures

In flight

Limited
Countermeasures &
Intensive Monitoring

Improved
Countermeasures &
Intensive Monitoring

**Effective Countermeasures/monitoring** 

Post flight

Medical Care & Intensive Rehab

Rehabilitation

**Maintenance of Health** 

1999

2006

2010



### Medicine of Extreme Environments

- Provide a national resource for developing databases and analysis of experience in the medicine of extreme environments
  - Polar medicine
  - Submarine analogs
  - Surface ship analogs
  - Contingency support experience/Military medicine
- Development of space medicine practice
  - Workshops co-sponsored by OCHMO and JSC
  - Develop "best practice" based on available evidence
- Explore analog opportunities
  - Underwater habitats
  - Remote site medical support
  - Confinement/isolation





### Medicine of Extreme Environments

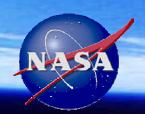
- Close liaison with Code M and JSC Medical Operations
  - Teaching opportunities
- Ongoing review/analysis of the Longitudinal Study of Astronaut Health
- Aerospace Medicine
  - Administrative support to Medical Policy Board
  - Support to NASA non-astronaut pilots
  - Intercenter Aviation Operations Panel (IAOP) participation
- Review and validation of health related research requirements and research deliverables





### Health Related Research Requirements and Deliverables

- New role for CHMO established by NASA Administrator
- Serves as the "FDA" of NASA
- Review and validation of health research requirements
  - Requirements articulated by Code M
    - Astronaut Corps
    - Flight Surgeons
    - Mission Support Personnel
- Review and validation of health research deliverables
  - Pharmacological regimens
  - Exercise protocols
  - Medical treatment protocols, etc.
- Reviews accomplished via panels or advisory groups with nationally recognized expertise in subject matter under review



Radiation

Stress

Noise/

**Vibration** 

### Major Health Issues

	On the Ground/
Risk	In the Atmosphere

Nonionizing & ionizing

 Increased skin cancer and cataract risk

Workforce stresses

• Multicultural work environments

• Extensive international travel

Physical hazards (noise)

Toxic exposures

• Ergonomic issues

Biohazards

• Physical hazards

In Space

• Exposure to solar and cosmic radiation

• Remote environment

 Multicultural, psychological, human factors issues

Leaving Earth/isolation

• Space systems engineering design

Confined environment

Biohazards

• Microgravity-induced physiologic changes

• Human-machine interfaces

Habitability/ Toxicology

+ Dysbarism, Countermeasures, Medical Care in Space



### Backup Material





### The Office of the Chief Health and Medical Officer

#### OCHMO will maintain oversight

- health and safety initiatives
- health care in space
- external review and accreditation
- research requirements and deliverables review

#### OCHMO will facilitate key agency programs

- support health care for each NASA field center
- women's health
- coordinate telemedicine technology transfer
- multicultural public health education
- agency-wide multi-phased Coping with Stress
- support NASA flight ops
- establish preventive and corrective actions based on critical health and safety issues

# From DOHA to (A)CHMO The Quest for a Suitable Acronym